# Exhibit 8

# GYNECARE PROLIFT*
# Pelvic Floor Repair System

**Total Pelvic Floor Repair**
**Anterior Pelvic Floor Repair**
**Posterior Pelvic Floor Repair**

# SURGICAL TECHNIQUE

*Tradmark

## Principles of the Procedure

The objective of the PROLIFT procedure is to achieve a complete anatomic repair of pelvic floor defects in a standardized way. Depending on the site of the defect and surgeon's preference, the repair can either be anterior, posterior, or total. The repair is achieved by the placement of one or two synthetic non-absorbable polypropylene (GYNEMESH* PS) mesh implants via a vaginal approach.

The procedure requires a wide dissection in order to properly place the relatively large implants. These implants are designed to cover all existing or potential pelvic floor defects in a tension free way.

### Hysterectomy

Surgeon's preference and the patient's needs will determine if a concurrent hysterectomy is required. Peritonealization is recommended to avoid contact of the mesh to the bowel when a hysterectomy is performed. Retrospective data analysis suggests that the rate of mesh exposure may be higher when performing the TransVaginal Mesh (TVM) procedure with concurrent hysterectomy.

### Vaginal Incisions

The principles regarding vaginal incisions include minimizing the size of the vaginal incisions and avoiding T-shaped incisions. Thus, when a vaginal hysterectomy is performed, it is recommended to avoid complementary sagittal incisions. This will dictate that the bladder dissection be performed through the pericervical incision.

### Mesh Fixation

The implants are held in place by friction acting on the associated straps passing through tissue. If required, additional stitches may be used along with the straps to aid in proper placement of the Implant. It is essential to install all of the available mesh straps to properly place and secure the implants.

### Vaginal Preservation

It is recommended to avoid large vaginal excisions and fixation of the vagina to the implant.

## Procedural Description

The procedure must be postponed if one of the following conditions is present:

- Vaginal infection
- Vaginal erosions
- Urinary infection

Additionally, the procedure should also be cancelled if a perioperative bladder or rectal injury occurs.

**Preoperative Preparation**

Repairs performed with the GYNECARE PROLIFT Pelvic Floor Repair System may be carried out under general or regional anesthesia according to surgeon's preference. Systematic preoperative antibiotic prophylaxis may be administered according to surgeon's preference.

The following steps are recommended prior to the start of the procedure:

- Antiseptic vaginal preparation
- Shaving or clipping of the pubic or vulvar hair
- Bowel preparation or preoperative enema
- Cleansing of the entire surgical area with appropriate antiseptic

The following steps are to be considered optional:

- Placement of an in-dwelling catheter after a urine culture has been performed
- Placement of lubricated packing in the rectum
- Infiltration of the vaginal wall by saline with a vasoconstrictive solution to ease dissection and reduce bleeding
- Administration of antibiotics

**Patient positioning**

The patient should be placed in the lithotomy position with her buttocks slightly overlapping the table and her thighs flexed at approximately 90 degrees in relation to the plane of the table.

## GYNECARE PROLIFT* Repair System

**Nomenclature**

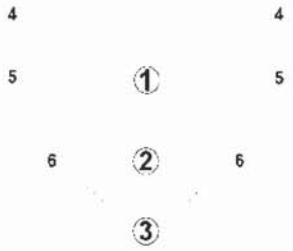
GYNECARE PROLIFT* Guide

GYNECARE PROLIFT* Cannula

GYNECARE PROLIFT* Retrieval Device


Anterior Implant


Posterior Implant




Total Implant

## Total Repair with Vaginal Hysterectomy

The procedure begins with a vaginal hysterectomy with or without adnexectomy, followed by an anterior repair and then a posterior repair. Retrospective data analysis suggests that the rate of mesh exposure may be higher when performing the TVM procedure with concurrent hysterectomy.

### Vaginal Incision and Hysterectomy

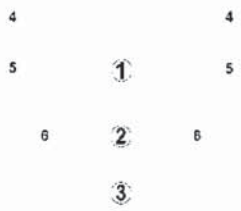
A standard vaginal hysterectomy is performed through a pericervical incision. It is recommended that users identify and retain the uterosacral ligaments or other elements of the cardinal ligament complex. These structures can later be interposed between the implant and the vagina or attached to the edges of the Total Implant according to surgeon's preference. Care must be taken to close the peritoneum.

The ensuing procedure steps will ideally be performed without any complementary sagittal incision whenever possible. Alternatively, a sagittal anterior colpotomy starting at the vaginal incision and ending approximately 1 cm from the bladder neck could be used if needed.

### Anterior Dissection

Grasp and maintain control of the anterior vaginal wall with a series of three atraumatic forceps. Perform a dissection of the entire thickness of the anterior vaginal wall. It is preferred to leave Halban's fascia (pubocervical fascia) on the vaginal wall. Dissection begins from the vaginal incision and should continue up to a point approximately 3-4 cm from the urinary meatus, in order to preserve and protect the region of the bladder neck.

Dissect the bladder laterally up to the vaginal cul de sac. When a defect exists, a finger will easily penetrate the paravesical fossa (paravaginal space). If no defect is evident, an orifice must be created in the fascia using blunt dissection techniques. This dissection is the starting point for a broad lateral dissection of the bladder, which will make it possible to identify the whole length of the arcus tendineus fascia pelvis (ATFP), which extends from the posterior aspect of the pubic arch to the ischial spine. If the ATFP cannot easily be identified, then palpation via a finger in the vagina from the pubic arch to the ischial spine should be used to ensure that straps 4 and 5 of the Anterior Segment (1) pass through at this level.




**Anterior Segment (1) of Total Implant**

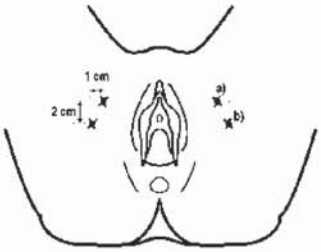
At this point, if required, plication of the bladder is performed in order to reduce the cystocele.

***Preparation for Placement of the Anterior Segment***

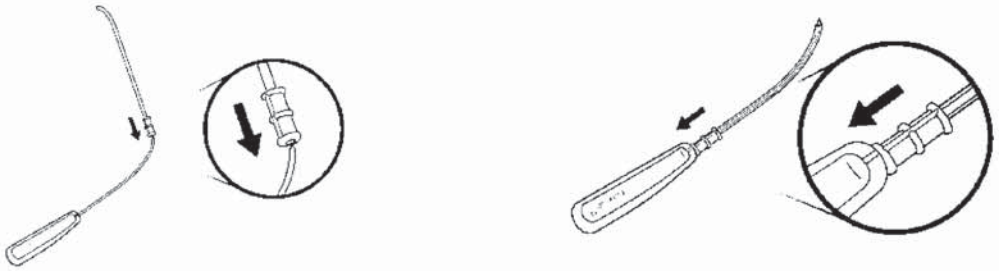
The following should be performed on the patient's left and right.

**The Superficial Straps**

The limits of the obturator foramen are identified by palpation between the thumb and index finger of the obturator membrane where it comes into contact with the bony boundaries. The cutaneous incision for passage of the superficial strap of the Anterior Segment (4) is made in the anteromedial edge of the obturator foramen, at the level of the urethral meatus. A 4 mm incision is made to enable the Guide with the Cannula installed to pass through the skin without tearing. It is helpful to mark the edge of the obturator foramen with a skin marking pen as a guide for the entrance locations.

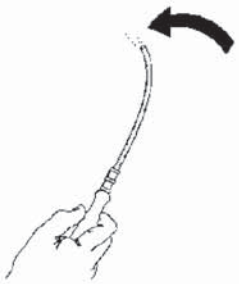



At the start of the passage, the Cannula-equipped Guide will perforate the obturator externus muscle and then the obturator membrane. The device should then be advanced medially through the obturator membrane and pass through the obturator internus muscle approximately 1 cm from the proximal (prepubic) end of the ATFP.



**Cannula-equipped Guide**

A finger positioned inside the vaginal dissection should always be used to ensure that the device follows the proper path and to provide protection to the bladder. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. Care should be taken to keep the Cannula in position, as the Guide is withdrawn to ensure that the tip of the Cannula remains slightly extended out of the tissue passage and the Cannula is not advanced further into the patient.



**Passage of Cannula-equipped Guide**

**Remove Guide and leave Cannula**

Once the Guide has been removed from the cannula, do not attempt to reinsert. Instead, remove the Cannula from the patient, reinstall the Guide, and then reinsert the Cannula into the patient.

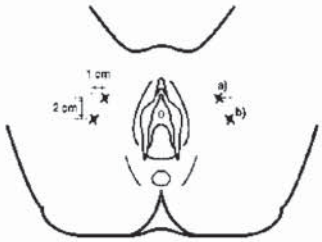
Following placement of the Cannula, the Retrieval Device is passed down and advanced out of the distal end of the installed Cannula. The looped end of the Retrieval Device is then retrieved through the vaginal dissection and pulled out of the vagina with an instrument or a finger.

**Pass Retrieval Device**

The proximal end of the Retrieval Device can then be passed through the loop and secured to the drape or a retractor, thus reserving the Retrieval Device for later use in pulling the Total Implant strap into position. Optionally, the Cannulas may also be secured when placed in order to limit movement as the other Cannulas are installed. Care should be taken to avoid movement of the Cannulas following placement.

**The Deep Straps**

For placement of the deep strap of the Anterior Segment, a second cutaneous incision is made 1 cm lateral and 2 cm below the preceding incision at the posterolateral edge of the obturator foramen. To provide protection of the bladder, a Breisky or similar long retractor may be placed in the dissection. The Guide and Cannula are then inserted through the obturator externus muscle and then through the obturator membrane. The device should follow a downward trajectory once it passes through the obturator membrane. This movement will enable the Cannula-equipped Guide to emerge through the obturator internus muscle at the bottom of the paravesical fossa behind the ATFP, approximately 1 cm from the ischial spine.




A finger positioned inside the vaginal dissection should be used to ensure that the Guide follows the proper path and to provide protection to the bladder. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. The Retrieval Device is then installed and secured as described above.

**Posterior Vaginal Incision**
The recommended incision for this repair is a complementary sagittal colpotomy of the lower / distal half of the vagina ending at the vulva. Alternatively, the dissection can be performed through a complementary transverse incision made at the junction of the perineal skin and the vagina. If a perineal repair is indicated, a diamond-shaped incision overlapping the lower half of the sagittal colpotomy and the posterior perineum is recommended.

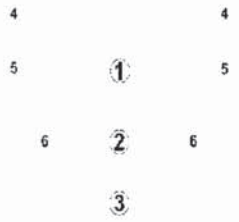
**Posterior Dissection**
Care should be taken when separating the rectum from the entire thickness of the vagina. Dissection of the entire thickness of the posterior vaginal wall should be performed starting from the vaginal incision and continued up to the apex of the vagina. Laterally, the dissection opens the pararectal spaces and follows the space between the rectum and the levator ani muscle until the sacrospinous ligament can be palpated.

Generally, this dissection enables placement of a Breisky retractor or other such instrument which will be useful during later activities. Further deep dissection should then be performed to expose both sides of the sacrospinous ligament at the level of the ischial spine.

At this point, if required, a plication of the prerectal fascia in order to reduce the rectocele should be performed. Any required reductions of enteroceles should also be performed at this time.

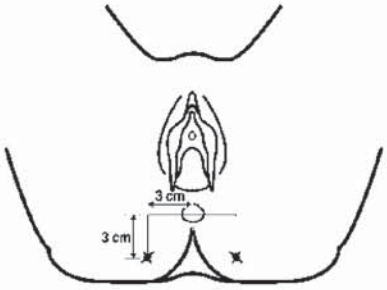
***Preparation for Placement of the Posterior Segment***

The following should be performed on the patient's left and right.



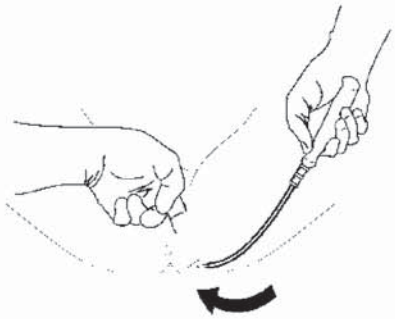

**Posterior Segment (3) of Total Implant**

The Posterior Segment (3) of the Total Implant is to be positioned in the ischioanal fossa, inferior to levator ani muscle, and secured by passage of the straps through the sacrospinous ligament and coccygeus muscles. To accomplish this, a 4 mm cutaneous incision is made approximately 3 cm lateral and 3 cm down from the anus.



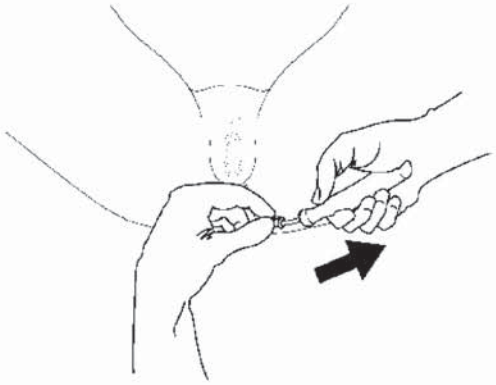

**Posterior incision**

The Cannula-equipped Guide is inserted into the incision, passed through the buttocks, and continued below the plane of the levator ani muscle, constantly controlled by the fingers within the vaginal dissection. The rectum should be pulled back and kept at a distance, either manually, or by using a retractor to prevent damage from the device.



**Insert Cannula-equipped Guide**

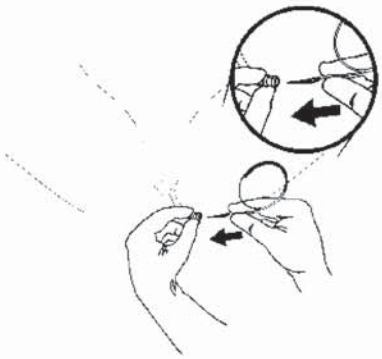
The Cannula-equipped Guide is advanced until it is in contact with the inferior side of the sacrospinous ligament approximately 3-4 cm medial to the ischial spine. It is then pushed through the sacrospinous ligament under digital control, thus exposing the tip of the Guide and Cannula. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. Care should be taken to keep the Cannula in position as the Guide is withdrawn to ensure that the tip of the Cannula remains extended out of the tissue passage and the Cannula is not advanced further into the patient.



**Remove Guide and leave Cannula**

Once the Guide has been removed from the cannula, do not attempt to reinsert. Instead, remove the Cannula from the patient, reinstall the Guide, and then reinsert the Cannula into the patient.

Following placement of the Cannula, the Retrieval Device is passed down and advanced out of the distal end of the Cannula.



**Pass Retrieval Device**

The looped end of the Retrieval Device is then retrieved through the vaginal dissection and pulled out of the vagina with an instrument or a finger.

**Retrieve the Retrieval Device**

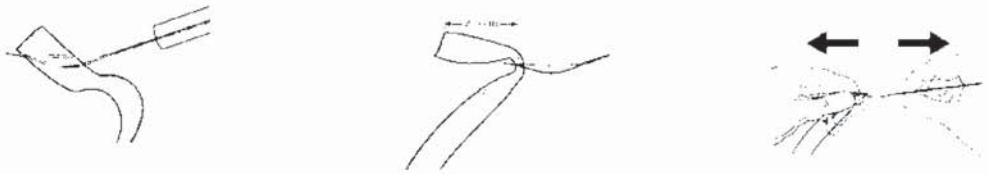
The proximal end of the Retrieval Device can then be passed through the loop and secured to the drape or a retractor with a hemostat, thus reserving the Retrieval Device for later use in pulling the Total Implant strap into position. Optionally, the Cannulas may also be secured when placed in order to limit movement as the other Cannulas are installed. Care should be taken to avoid movement of the Cannulas following placement.

An alternative approach is to directly fixate the Posterior Segment straps (6) to the superficial aspect of the sacrospinous ligament. This can be accomplished by trimming the distal portion of these straps to the proper length and performing fixation with suture or alternative fixation means.


**Straps (6 ) of Posterior Segment**

***Placement of the Total Implant***

**Anterior Segment Placement**
Placement of the Total Implant starts anteriorly. The distal ends of the Total Implant straps are sequentially captured in the loops at the end of the Retrieval Devices.



**Capture distal ends**

The loops are then pulled through the Cannulas to the proximal exit. The ends of the straps of the Anterior Segment are uniquely shaped with the superficial straps having squared ends and the deep straps having triangular ends.

**Pull loops through Cannula**

Optimally, the Anterior Segment of the Total Implant will be positioned tension-free under the bladder while ensuring lateral contact against the ATFP. Lateral contact of the Total Implant to the ATFP should be carefully verified.

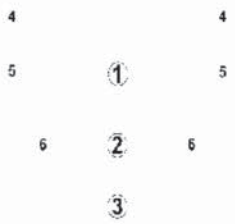
If required, small reductions in the dimensions of the Total Implant to ensure proper fit should be performed at this point.

Further fine adjustment of the tension and position of the Total Implant may be performed following closure of the vaginal incisions at the end of the procedure.

Fixing the Total Implant at each of the pubic insertions of the puborectalis muscle with sutures is optional. If the surgeon elects to do this, it is essential that the anterior notch of the Total Implant leaves the neck of the bladder largely free. Additional fixations remain optional.

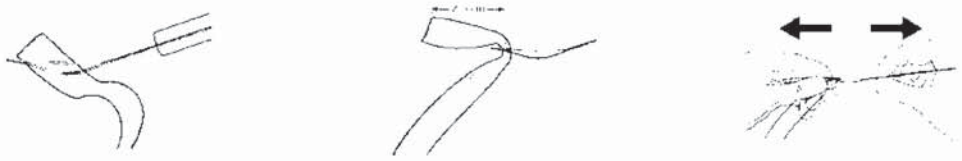
In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh, it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

**Middle Segment Placement**
The Middle Segment (2) of the Total Implant should be positioned in the posterior dissection behind the vaginal apex. The uterosacral ligaments or other elements of the cardinal ligament complex can be either interposed between the Total Implant and the vagina or attached to the edges of the Total Implant according to surgeon's preference.




**Middle Segment (2) of Total Implant**

**Posterior Segment Placement**
Installation of the Posterior Segment of the Total Implant requires the distal ends of the straps to be sequentially captured in the loops at the end of the Retrieval Devices.



**Capture distal ends**

The loops are then pulled through the Cannulas to the proximal exit. The Posterior Segment can be positioned once both straps have been retrieved.

Optimally, the Posterior Segment of the Total Implant will be positioned tension-free above the rectum with its lateral edges against the superior surface of the levator ani muscles. Minor reductions in Total Implant length should be made at this point, if required, to ensure proper fit. If desired, sutures may be used bilaterally on the levator ani muscles at the external edge of the Total Implant to ensure aid in positioning.

Further fine adjustment of the tension and position of the Total Implant may be performed following closure of the vaginal incisions at the end of the procedure.

An alternative approach to fixation of the Posterior Segment is to directly fixate the straps (6) to the superficial aspect of the sacrospinous ligament. This can be accomplished by trimming the distal portion of the straps (6) to the proper length and fixating with suture or other alternative means.


**Straps (6) of Posterior Segment**

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh, it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

**Vaginal Closure and Final Adjustment**
Closure of the vaginal incisions can be made according to surgeon's preference. The straps should be used to make any required additional fine adjustment to the Total Implant position, taking care to not place the mesh under tension. The Cannulas can be withdrawn once the Total Implant is properly positioned. The ends of the Total Implant straps extending out of the cutaneous incisions should be trimmed at the level of the dermis. These incisions are closed according to surgeon's preference.

## Total Repair with Uterine Preservation

Surgeon's preference and the patient's needs will determine if a concurrent hysterectomy is required. If the uterus is maintained, the following information includes important differences of the procedure previously described.

### Implant Preparation

The Total Implant must be cut at the midpoint of the Middle Segment (2).


**Middle Segment (2) of Total Implant**

### Anterior Vaginal Incision

The recommended incision for this repair is a sagittal colpotomy starting 1 cm below the cervix and ending approximately 1 cm from the bladder neck. Alternatively, a transverse incision could be used.

### Anterior Mesh Fixation

The posterior part of the Anterior Segment should be attached to the anterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of PROLENE suture.

### Posterior Vaginal Incision

The recommended incision for this repair is a sagittal colpotomy of the lower half of the vagina ending at the vulva. Alternatively, the dissection could be performed through a transverse incision of the perineum made at the junction of the perineal skin and the vagina. If a perineal repair is indicated, a diamond-shaped incision overlapping the lower half of the sagittal colpotomy and the posterior perineum is recommended.

### Posterior Mesh Fixation

The anterior portion of the Posterior Segment is attached to the posterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of PROLENE suture.

## Total Repair in Case of Previous Hysterectomy

The following details important differences associated with women who have had a prior hysterectomy.

### Vaginal Incision

The recommended incision for this repair is a sagittal colpotomy starting about 1 cm above the vaginal scar and ending approximately 1 cm from the bladder neck. Alternatively, a transverse incision could be used.

### Mesh Fixation

Generally, there is no structure that can readily be identified for attachment to the central region of the implant. If the uterosacral ligaments exist, they can be used in the same way as previously described.

## Total Repair in the Absence of a Posterior Defect (Anterior / Apical Repair)

When the patient presents the association of a cystocele and a hysterocele or a vaginal vault prolapse but no significant posterior defect (rectocele), the PROLIFT Total Pelvic Floor Repair kit may also be used to perform a combination anterior/apical repair.

This repair is accomplished by the following:

- Performing the required anterior and posterior incisions and dissection
- Removing the unneeded lower part of the Posterior Segment of the Total Implant (straps must be left intact)
- Placing the Anterior Segment per standard procedures
- Placing and fixing the Middle Segment per standard procedures
- Securing the straps of the abbreviated Posterior Segment to or through the sacrospinous ligament as previously described

The suspension of the uterus (in case of uterine preservation) or the vaginal vault (in case of concomitant or previous hysterectomy) relies on the Posterior Segment of the Total Implant.

In case of uterine conservation, the anterior part of the Posterior Segment of the Total Implant is attached to the posterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of non absorbable monofilament suture.

## Anterior Repair with Hysterectomy

### Vaginal Incision and Hysterectomy

A standard vaginal hysterectomy is performed through a pericervical incision. It is recommended that users identify and retain the uterosacral ligaments or other elements of the cardinal ligament complex. These structures can later be interposed between the Anterior Implant and the vagina or attached to the edges of the Anterior Implant according to surgeon's preference. Care must be taken to close the peritoneum.

The next steps will ideally be performed without any complementary sagittal incision whenever possible. Alternatively, a sagittal anterior colpotomy starting at the vaginal incision and ending approximately 1 cm from the bladder neck could be used if needed.

### Anterior Dissection

Grasp and maintain control of the anterior vaginal wall with a series of three atraumatic forceps. Perform a dissection of the entire thickness of the anterior vaginal wall. It is preferred to leave Halban's fascia (pubocervical fascia) on the vaginal wall. Dissection begins from the vaginal incision and should continue up to a point approximately 3-4 cm from the urinary meatus, in order to preserve and protect the region of the bladder neck.

Dissect the bladder laterally up to the vaginal cul de sac. When a defect exists, a finger will easily penetrate the paravesical fossa (paravaginal space). If no defect is evident, an orifice must be created in the fascia using blunt dissection techniques. This dissection is the starting point for a broad lateral dissection of the bladder, which will make it possible to identify the whole length of the arcus tendineus fascia pelvis (ATFP), which extends from the posterior aspect of the pubic arch to the ischial spine. If the ATFP cannot easily be identified, then palpation via a finger in the vagina from the pubic arch to the ischial spine should be used to ensure that straps 4 and 5 of the Anterior Implant pass through at this level.


**Anterior Implant**

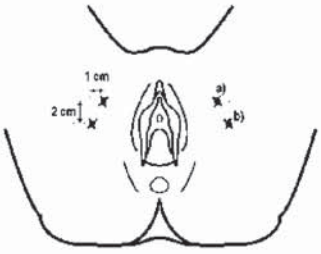
At this point, if required, plication of the bladder is performed in order to reduce the cystocele.

***Preparation for Placement of the Anterior Implant***

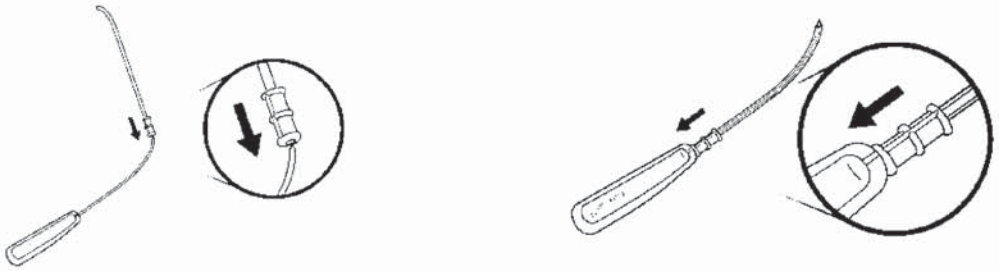
The following should be performed on the patient's left and right.

**The Superficial Straps**

The limits of the obturator foramen are identified by palpation between the thumb and index finger of the obturator membrane where it comes into contact with the bony boundaries. The cutaneous incision for passage of the superficial strap (4) of the Anterior Implant is made in the anteromedial edge of the obturator foramen, at the level of the urethral meatus. A 4 mm incision is made to enable the Guide with the Cannula installed to pass through the skin without tearing. It is helpful to mark the edge of the obturator foramen with a skin marking pen as a guide for the entrance locations.




At the start of the passage, the Cannula-equipped Guide will perforate the obturator externus muscle and then the obturator membrane. The device should then be advanced medially through the obturator membrane and pass through the obturator internus muscle approximately 1 cm from the proximal (prepubic) end of the ATFP.



**Cannula-equipped Guide**

A finger positioned inside the vaginal dissection should always be used to ensure that the device follows the proper path and to provide protection to the bladder. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. Care should be taken to keep the Cannula in position as the Guide is withdrawn to ensure that the tip of the Cannula remains slightly extended out of the tissue passage and the Cannula is not advanced further into the patient.

**Passage of Cannula-equipped Guide**

**Remove Guide and leave Cannula**

Once the Guide has been removed from the cannula, do not attempt to reinsert. Instead, remove the Cannula from the patient, reinstall the Guide, and then reinsert the Cannula into the patient.

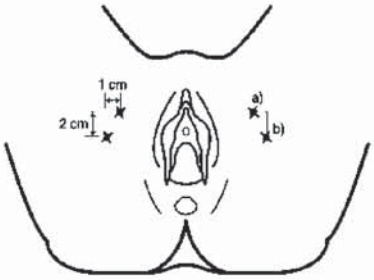
Following placement of the Cannula, the Retrieval Device is passed down and advanced out of the distal end of the installed Cannula. The looped end of the Retrieval Device is then retrieved through the vaginal dissection and pulled out of the vagina with an instrument or a finger.

**Pass Retrieval Device**

The proximal end of the Retrieval Device can then be passed through the loop and secured to the drape or a retractor, thus reserving the Retrieval Device for later use in pulling the Implant strap into position. Optionally, the Cannulas may also be secured when placed in order to limit movement as the other Cannulas are installed. Care should be taken to avoid movement of the Cannulas following placement.

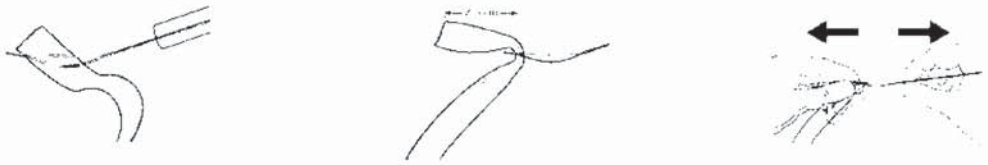
**The Deep Straps**

For placement of the deep strap (5) of the Anterior Implant, a second cutaneous incision is made 1 cm lateral and 2 cm below the preceding incision at the posterolateral edge of the obturator foramen. To provide protection of the bladder, a Breisky or similar long retractor may be placed in the dissection. The Guide and Cannula are then inserted through the obturator externus muscle and then through the obturator membrane. The device should follow a downward trajectory once it passes through the obturator membrane. This movement will enable the Cannula-equipped Guide to emerge through the obturator internus muscle at the bottom of the paravesical fossa behind the ATFP, approximately 1 cm from the ischial spine.




A finger positioned inside the vaginal dissection should be used to ensure that the Guide follows the proper path and to provide protection to the bladder. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. The Retrieval Device is then installed and secured as described above.

**Placement of the Anterior Implant**
The distal ends of the Anterior Implant straps are sequentially captured in the loops at the end of the Retrieval Devices.



**Capture distal ends**

The loops are then pulled through the Cannulas to the proximal exit. The ends of the straps of the Anterior Implant are uniquely shaped with the superficial straps having squared ends and the deep straps having triangular ends.

**Pull loops through Cannula**

The Anterior Implant can be carefully positioned once all straps have been retrieved. Optimally, the Anterior Implant will be positioned tension-free under the bladder while ensuring lateral contact against the ATFP. Lateral contact of the Anterior Implant to the ATFP should be carefully verified. If required, small reductions in the dimensions of the Anterior Implant to ensure proper fit should be performed at this point.

Further fine adjustment of the tension and position of the Anterior Implant may be performed following closure of the vaginal incisions at the end of the procedure.

Fixing the Anterior Implant at each of the pubic insertions of the puborectalis muscle with sutures is optional. If the surgeon elects to do this, it is essential that the anterior notch of the Anterior Implant leaves the neck of the bladder largely free.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

The Posterior Tail (7) of the Anterior Implant can be left free, positioned under the inferior margin of the bladder, or attached to the parametrial / cardinal or uterosacral ligaments according to the surgeon's preference. Additional fixations remain optional.


**Posterior Tail (7) of Anterior Implant**

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

**Vaginal Closure and Final Adjustment**

Closure of the vaginal incisions can be made according to surgeon's preference. The straps should be used to make any required additional fine adjustment to implant position, taking care to not place the mesh under tension. Following proper positioning, the Cannulas can be carefully withdrawn.

The ends of the Anterior Implant straps extending out of the cutaneous incisions of the obturator foramen should be trimmed at the level of the dermis. These incisions are then closed according to surgeon's preference.

## Anterior Repair with Uterine Preservation

The following includes important differences associated with the procedure when the uterus is preserved:

### Anterior Vaginal Incision

The recommended incision for this repair is a sagittal colpotomy starting 1 cm below the cervix and ending approximately 1 cm from the bladder neck. Alternatively, a transversal incision could be used.

### Anterior Mesh Fixation

The Posterior Tail (7) of the Anterior Implant is attached to the anterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of PROLENE suture.


**Posterior Tail (7) of Anterior Implant**

## Posterior Repair with Hysterectomy

### Vaginal Incision and Vaginal Hysterectomy

A standard vaginal hysterectomy is performed through a pericervical incision. It is recommended that users identify and retain the uterosacral ligaments or other elements of the cardinal ligament complex. These structures can later either be interposed between the Posterior Implant and the vagina or attached to the edges of the Posterior Implant according to surgeon's preference. Care must be taken to close the peritoneum.

### Posterior Vaginal Incision

The recommended incision for this repair is a complementary sagittal colpotomy of the lower / distal half of the vagina ending at the vulva. Alternatively, the dissection can be performed through a complementary transverse incision made at the junction of the perineal skin and the vagina. If a perineal repair is indicated, a diamond-shaped incision overlapping the lower half of the sagittal colpotomy and the posterior perineum is recommended.

### Posterior Dissection

Care should be taken to accomplish separation of the rectum from the entire thickness of the vagina. Perform a dissection of the entire thickness of the posterior vaginal wall. Dissection starts from the vaginal incision and should be continued up to the apex of the vagina. Laterally, the dissection opens the pararectal spaces and follows the space between the rectum and the levator ani muscle until the sacrospinous ligament can be palpated. Generally, this dissection allows placement of a tool such as a Breisky retractor or other such instrument which will be useful during later activities. Further deep dissection should then be performed on both sides to expose or palpate the distal part of the sacrospinous ligament at the level of the ischial spine.

At this point, if required, a plication of the prerectal fascia in order to reduce the rectocele should be performed. Any required reductions of enteroceles should also be done at this time.

### *Preparation for Placement of the Posterior Implant*

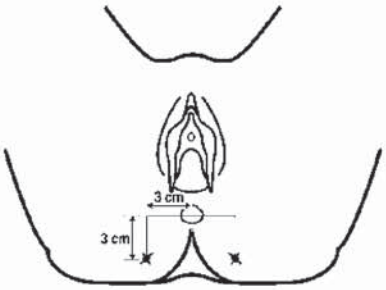
Two approaches for fixating the Posterior Implant are suggested.

### Transgluteal Fixation

The straps of the Posterior Implant are passed transgluteally and secured by passage of the straps through the sacrospinous ligament and coccygeus muscle.

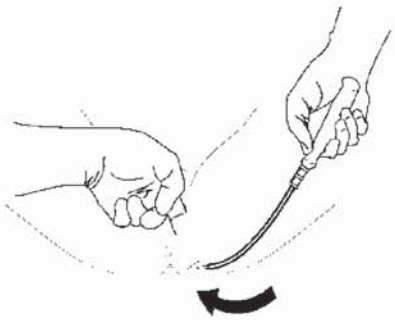

**Posterior Implant**

To accomplish this, a 4 mm cutaneous incision is made approximately 3 cm lateral and 3 cm down from the anus. If desired, sterile packing coated with lubricant may be inserted into the rectum first to ensure better appreciation of the position of the rectal ampulla.



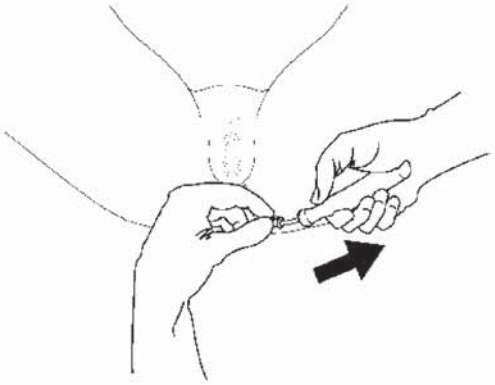

**Posterior Incision**

The Cannula-equipped Guide is inserted into the incision, passed through the buttocks, and continued below the plane of the levator ani muscle, constantly controlled by the fingers within the vaginal dissection. The rectum should be pulled back and kept at a distance, either manually, or by using a retractor to prevent damage from the device.



**Insert Cannula-equipped Guide**

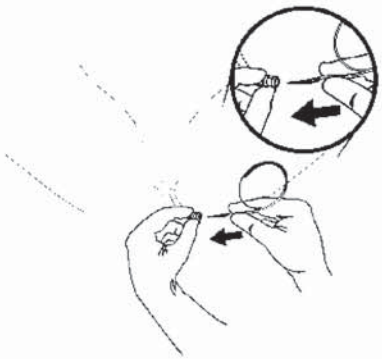
The device is advanced until it is in contact with the inferior side of the sacrospinous ligament approximately 3-4 cm medial to the ischial spine. The device is pushed through the sacrospinous ligament under digital control, thus exposing the tip of the Guide and Cannula. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. Care should be taken to keep the Cannula in position as the Guide is withdrawn to ensure that the tip of the Cannula remains extended out of the tissue passage and the Cannula is not advanced further into the patient.



**Remove Guide and leave Cannula**

Once the Guide has been removed from the cannula, do not attempt to reinsert. Instead, remove the Cannula from the patient, reinstall the Guide, and then reinsert the Cannula into the patient.

Following placement of the Cannula, the Retrieval Device is passed down and advanced out of the distal end of the Cannula.



**Pass Retrieval Device**

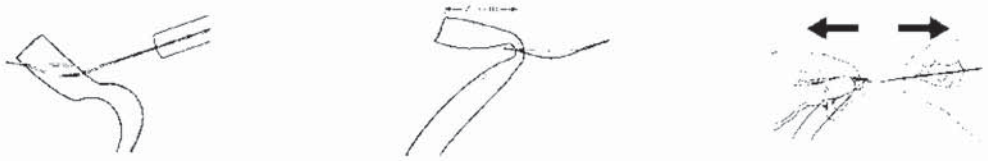
The looped end of the Retrieval Device is then retrieved through the vaginal dissection and pulled out of the vagina with an instrument or a finger.

**Retrieve the Retrieval Device**

The proximal end of the Retrieval Device can then be passed through the loop and secured to the drape or a retractor with a hemostat, thus reserving the Retrieval Device for later use in pulling the Posterior Implant strap into position. Optionally, the Cannulas may also be secured when placed in order to limit movement as the other Cannulas are installed. Care should be taken to avoid movement of the Cannulas following placement.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

**Placement of the Posterior Implant**
To install the Posterior Implant, the distal ends of the straps are captured in the loops at the end of the Retrieval Devices. The loops are then pulled through the Cannulas to the proximal exit.

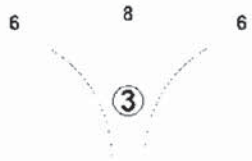


**Capture distal ends**

The Posterior Implant can be positioned once both straps have been retrieved. Optimally, the Posterior Implant will be positioned tension-free above the rectum with its lateral edges against the anterior face of the levator ani muscles.

Minor reductions in Posterior Implant length should be made at this point to ensure proper fit. If desired, sutures may be used bilaterally on the levator ani at the external edge of the Posterior Implant to ensure aid in positioning. A further fine adjustment of the tension and position of the Posterior Implant may be performed following closure of the vaginal incisions at the end of the procedure.

Alternatively, the straps (6) of the Posterior Implant may be fixated directly to the superficial aspect of the sacrospinous ligament. This can be accomplished by trimming the distal portion of these straps to the proper length and performing fixation with suture or alternative fixation means.




**Posterior Implant**

The Anterior Segment (8) of the Posterior Implant can be left free, or positioned above the Pouch of Douglas, or attached to the cardinal or uterosacral ligaments according to the surgeon's preference.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

**Vaginal Closure and Final Adjustment**
Closure of the vaginal incisions can now be made according to surgeon's preference. The straps should now be used to make any required additional fine adjustment to the Posterior Implant position, taking care to not place the mesh under tension. Following proper positioning, the Cannulas can be carefully withdrawn.

The ends of the straps extending out of the cutaneous incisions of the obturator foramen should be trimmed at the level of the dermis. These incisions are then closed according to surgeon's preference.

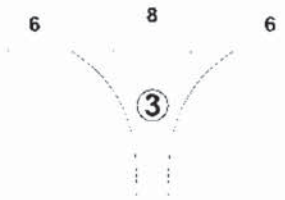
## Posterior Repair with Uterine Preservation

The following includes important differences associated with the procedure when the uterus is preserved.

**Posterior Vaginal Incision**
The recommended incision for this repair is a sagittal colpotomy of the lower half of the vagina ending at the vulva. Alternatively, the dissection could be performed through a transverse incision made at the junction of the perineal skin and the vagina. If a perineal repair is indicated, a diamond-shaped incision overlapping the lower half of the sagittal colpotomy and the posterior perineum is recommended.

**Posterior Dissection**
The posterior dissection is performed up to the uterine isthmus.

**Posterior Mesh Fixation**
The Anterior Segment (8) of the Posterior Implant is attached to the posterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of PROLENE suture.




**Anterior Segment (8) of Posterior Implant**

**Associated Procedures**
Whenever needed, a perineal repair or a suburethral sling for the treatment of stress urinary incontinence can be performed. The suburethral sling can be passed through the retropubic space or obturator foramen depending on surgeon's preference.

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